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EXAMINER

RAMIREZ, DELIA M

ART UNIT PAPER NUMBER

1652

DATE MAILED: 08/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/993,059

Applicant(s)

GARGER ET AL.

Examiner

Delia M. Ramirez

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 June 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 19-66 is/are pending in the application.
- 4a) Of the above claim(s) 19-30,36 and 42-66 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 31-35 and 37-41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5-7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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## **DETAILED ACTION**

### ***Status of the Application***

Claims 19-66 are pending.

It is noted that the examination of the instant application has been assigned to a different Examiner in Group Art Unit 1652.

Applicant's election without traverse of Group III, claims 31-35 and 37-41 drawn to a polypeptide comprising SEQ ID NO: 30, as well as the election of SEQ ID NO: 18, in Paper No. 10, filed on 8/24/2003 is acknowledged.

Claims 19-30, 36, and 42-66 are withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

### ***Specification***

1. The specification is objected to due to the presence of blank spaces. See page 22, line 23, after the term "Accession No.". Appropriate correction is required.
2. The abstract is objected to due to the recitation of "-galactosidase" in line 1. The abstract should be amended to recite " $\alpha$ -galactosidase A". Appropriate correction is required.

### ***Priority***

3. Acknowledgment is made of a claim for domestic priority under 35 U.S.C. 120 or 121 to US application No. 09/626,127 filed on 07/26/2000.

***Information Disclosure Statement***

4. The information disclosure statements (IDS) submitted on 5/2/2002 (Paper No. 5), 7/23/2002 (Paper No. 6), and 1/8/2003 (Paper No. 7) are acknowledged. The references listed in Paper No. 5 as "Brady, Fabry Disease" and "Desknick et al.,  $\alpha$ -galactosidase A deficiency" are not in conformance with MPEP § 609 and have not been considered for the following reasons. No publication date has been indicated for the instant references, a search of said references in the non-patented literature could not be made, and no copy of said reference has been provided. Furthermore, the Brady reference lacks the name of the journal or book where it was published. The remaining references are in compliance with the provisions of 37 CFR 1.97. Accordingly, such references are being considered by the examiner.

***Drawings***

5. The drawings have been reviewed and are approved by a draftsperson under 37 CFR 1.84 or 1.152.

***Claim Objections***

6. Claims 31-35 and 37-41 are objected to due to the recitation of "rGAL-12R" and "GlcNac". Abbreviations unless otherwise obvious and/or commonly used in the art, should not be recited in the claims without at least once reciting the entire phrase for which the abbreviation is used. It is suggested that in the case of "rGAL-12R", the claim be amended to indicate what it represents, e.g., if a polypeptide, a SEQ ID NO: # should be recited. In the case of "GlcNac", it

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is suggested that the term "N-acetylglucosamine" be added next to it at least once. Appropriate correction is required.

7. Claim 31 is objected to due to the recitation of "C-terminus of said polypeptide is the amino acid sequence depicted in SEQ ID NO: 30". Since a polypeptide is a molecule and a sequence is a graphical representation of the order in which residues are arranged in a molecule, it is suggested that for clarity, the term be amended to recite "C-terminus of said polypeptide has the amino acid sequence depicted in SEQ ID NO: 30" or similar. Appropriate correction is required.

***Claim Rejections - 35 USC § 101***

8. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

9. Claims 31-35 and 37-41 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 31-35 and 37-41, as written, do not sufficiently distinguish over polypeptides as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter.

See *Diamond v. Chakrabarty*, 447 US 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "isolated" or "purified" as taught by pages 64-69 of the specification. See MPEP 2105.

***Claim Rejections - 35 USC § 112, Second Paragraph***

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 31-35 and 37-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

12. Claims 31 and 37 (claims 32-35 and 38-41 dependent thereon) are indefinite in the recitation of "amino acid sequence of rGAL-12R" for the following reasons. While the term appears to indicate that rGAL-12R is a polypeptide and the specification seems to suggest that rGAL-12R has the amino acid sequence set forth in SEQ ID NO: 18 (page 16, lines 1-5), the specification also teaches that rGAL-12R is a vector. See, for example, page 65, Table 10 under Vector Designation, or page 69, line 12. As such, it is unclear as to how a vector, which is a nucleic acid, can have an amino acid sequence. For examination purposes, it will be assumed that the intended meaning of the term is "amino acid sequence of SEQ ID NO: 18". Correction is required.

13. Claims 32-35 and 38-41 are indefinite in the recitation of "amino acid positions....relative to rGAL-12R" for the following reasons. As indicated above, it is unclear as to what rGAL-12R represents. If it is a vector, it is unclear as to how a vector can have amino acids. For examination purposes, it will be assumed that the intended meaning of the term is "amino acid positions ....of SEQ ID NO: 18". Correction is required.

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14. Claims 38-41 are indefinite in the recitation of “the polypeptide according to claim 37, wherein said polypeptide ...” for the following reasons. Claim 37, from which claims 38-41 depend upon, is directed to a polypeptide consisting of the amino acid sequence of SEQ ID NO: 18. See above for claim interpretation of claim 37. The term “consisting of” in claim 37 implies that no additional structural elements are allowed in said polypeptide. Therefore, it is unclear as to how the polypeptide of claim 37 can have other structural limitations such as those recited in claims 38-41. It is suggested that dependent claims 38-41 be amended to be independent claims reciting “A polypeptide consisting of the amino acid sequence of SEQ ID NO: 18 wherein said polypeptide is glycosylated....”, “A polypeptide consisting of the amino acid sequence of SEQ ID NO: 18 wherein said polypeptide has a plant glycosylation pattern....”, or similar. For examination purposes, the proposed language will be used. Correction is required.

### ***Double Patenting***

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claims 31-35 and 37-41 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 7 of copending Application

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No. 10/103327. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other. Claim 7 of copending Application No. 10/103327 (published as U.S. Publication No. 20030106095) is partially directed to the polypeptide of SEQ ID NO: 18. Claims 31 and 37 of the instant application are directed to a polypeptide comprising the amino acid sequence of SEQ ID NO: 18 wherein the C-terminus of said polypeptide has the amino acid sequence of SEQ ID NO: 30. Claims 32-45 and 38-41 of the instant application are directed to the polypeptide of SEQ ID NO: 18 wherein said polypeptide is (1) glycosylated at positions 108, 161, 184, or 337, (2) glycosylated at positions 108, 161 and 184 such that a  $\beta$ -1,2 xylose is present on a  $\beta$ -linked mannose of the core, or (3) glycosylated at positions 108, 161 and 184 such that an  $\alpha$ -1,3 fucose is present on the proximal N-acetylglucosamine (GlcNac). Claims 31-35 and 37-41 cannot be considered patentably distinct from claim 7 of copending Application No. 10/103327 since SEQ ID NO: 18 comprises SEQ ID NO: 30, and also in view of the disclosure in copending Application No. 10/103327 of modified human  $\alpha$ -galactosidase A having the specific glycosylation patterns described in (1)-(3) above (paragraphs 293-295 of U.S. Publication No. 20030106095) as embodiments which would anticipate claims 32-35 and 38-41. As such, claim 7 of copending Application No. 10/103327



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anticipates claims 31 and 37, and the specific embodiments disclosed in paragraphs 293-295 of copending Application No. 10/103327 render claims 32-35 and 38-41 prima facie obvious.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Allowable Subject Matter***

17. Claims 31-35 and 37-41 appear to be allowable over the prior art of record.


***Conclusion***

18. No claim is in condition for allowance.

19. Applicants are requested to submit a clean copy of the pending claims (including amendments, if any) in future written communications to aid in the examination of this application.

20. Certain papers related to this application may be submitted to Art Unit 1652 by facsimile transmission. The FAX number is (703) 308-4556. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If Applicant submits a paper by FAX, the original copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (703) 306-0288. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (703) 308-3804. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
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Art Unit 1652